

SEP 10 1996

K963181

## 510(k) Summary

### Elecsys® CalCheck™ T Uptake

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<b>Introduction</b>	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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<b>1) Submitter name, address, contact</b>	Boehringer Mannheim Corporation 9115 Hague Rd. Indianapolis, IN 46250 (317) 845-2000  Contact Person: John D. Stevens  Date Prepared: August 12, 1996
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<b>2) Device name</b>	Proprietary name: Elecsys CalCheck T Uptake  Common name: Calibration Verification Material  Classification name: Single (specified) analyte controls (assayed + unassayed)
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<b>3) Predicate device</b>	We claim substantial equivalence to the Tosoh Medic AIA-Pack HCG Calibration Verification Test Set, K924862. The intended use for both products is to verify the calibration curve of automated immunoassay analyzers
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<b>4) Device Description</b>	The Elecsys CalCheck T Uptake is a three level single analyte set of lyophilized, human based materials. After reconstitution they are assayed in triplicate and the results are compared to the target values.
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<b>5) Intended use</b>	Elecsys CalCheck T Uptake is intended for use in the quantitative verification of the calibration curve established by the Elecsys T Uptake reagents and calibrators on Elecsys 1010 or 2010 immunoassay analyzers.
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## 510(k) Summary, Elecsys® CalCheck™ T Uptake, Continued

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**6) Comparison  
to predicate  
device**

The Boehringer Mannheim Elecsys CalCheck T Uptake is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Tosoh Medics AIA-Pack HCG Calibration Verification Test Set, K924862.

The intended use of both the Elecsys CalCheck T Uptake and the predicate device are the same in that they are intended to be used for the calibration verification for their labeled analytes on automated immunoassay analyzers.